K092047 p. 1/2

510(k) Summary

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, #100
Austin, TX 78754-3832

JAN 14 2010

510(k) CONTACT: Debbie Stearns
Phone: (512) 836-5001 x1548

TRADE NAME: Ascension® Metal Great Toe System

COMMON NAME: Toe joint phalangeal (hemi-toe) polymer prosthesis

CLASSIFICATION: 21 CFR 888.3730 (hemi)

PRODUCT CODE: KWD

PANEL: Orthopedic

PREDICATE DEVICES:

K031859 – CAP Great Toe Resurfacing Hemi-arthroplasty implant
K023770 – K2 Hemi Toe Implant System

DEVICE DESCRIPTION:
The Ascension® Metal Great Toe System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The components are anatomically designed, monolithic devices designed for resurfacing of the head of the 1st metatarsal or the phalangeal (MTP) joint. The devices are made from cobalt chromium alloy with a commercially pure titanium plasma spray. These devices are intended as hemi-arthroplasties at either surface and are press-fit.
Each device is boxed individually and delivered sterile for single use.

INTENDED USE:
The Ascension® Metal Great Toe System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemi-arthroplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock. Indications include:

- Hallux valgus or Hallux limitus
- Hallux rigidus
- Unstable or painful metatarsal/phalangeal (MTP) joint

BASIS OF SUBSTANTIAL EQUIVALENCE:

There are no significant differences between the Ascension Metal Great Toe System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ascension Orthopedics, Inc.
% Ms. Debbie Stearns
Director, Regulatory/Clinical Affairs
8700 Cameron Road, #100
Austin, Texas 78754-3832

JAN 1 4 2010

Re: K092047
Trade/Device Name: Ascension Metal Great Toe System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: December 18, 2009
Received: December 22, 2009

Dear Ms. Stearns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092047 p. 1/1

Indications for Use Statement

510(K) Number: K

Device Name: Ascension® Metal Great Toe System

Indications for Use:

The Ascension® Metal Great Toe System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemi-arthroplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock. Indications include:

- Hallux valgus or Hallux limitus
- Hallux rigidus
- Unstable or painful metatarsal/phalangeal (MTP) joint

Prescription Use X OR Over-The-Counter Use

(Part 21 CFR 801Subpart B) (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

10

510(k) Number K092047